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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/628,296	07/28/2003	Lian-Chao Li	P06331US01	4176

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EXAMINER

KUMAR, VINOD

ART UNIT PAPER NUMBER

1638

DATE MAILED: 11/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

10/628,296

**Applicant(s)**

LI ET AL.

**Examiner**

Vinod Kumar

**Art Unit**

1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 05 September 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-5, 8-12 and 22-37 is/are pending in the application.
- 4a) Of the above claim(s) 1-5, 8-12 and 22-29 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 30-37 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 July 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

***DETAILED ACTION***

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
2. The objections to specification are withdrawn in light of amendments to the specification.
3. The rejections of claims 6-7 and 14-21 under 35 U.S.C. 112, second paragraph, are withdrawn in light of claim amendments.
4. The rejection of claims 20-21 under 35 U.S.C. 101, is withdrawn in light of claim amendments.

***Claim Rejections - 35 USC § 101***

5. Claims 30-37 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. This rejection has been necessitated due to claim amendments.

Claims 30-37 read on a protein preparation per se, which is found in nature and thus, is unpatentable to Applicants. The protein preparation comprising a group 2/3 pollen allergen, as claimed in claims 30-37, has the same characteristics as those found or produced naturally or as cellular precursors thereof and therefore does not constitute

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patentable subject matter. As "carrier" is not defined, the claimed preparation reads on a naturally occurring product. See *American Wood v. Fiber Disintegrating Co.*, 90 U.S. 566 (1974), *American Fruit Growers v. Brodgex Co.*, 283 U.S. 2 (1931), *Funk Brothers Seed Co. v. Kalo Inoculant Co.*, 33 U.S. 127 (1948), *Diamond v. Chakrabarty*, 206 USPQ 193 (1980).

***Claim Rejections-35 USC § 112***

6. Claims 30-37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly out and distinctly claim the subject matter which Applicant regards the invention. This rejection has been necessitated due to claim amendments.

Claim 30 is rejected under 112, second paragraph as being indefinite in its recitation "carrier", which is confusing, since it is unclear which "carrier" is being referred to. Is it a proteinaceous or non-proteinaceous material? What is the relationship of "carrier" with a group 2/3 pollen allergen in the protein preparation. Specification does not define the recitation "carrier". It is unclear what is intended?

Claim 36 is rejected under 112, second paragraph as being indefinite in its recitation "preparation further includes  $\beta$ -expansin", which is confusing since it is unclear how a protein preparation comprising a group 2/3 pollen allergen with  $\beta$ -expansin activity further comprises another  $\beta$ -expansin protein. Does it mean the protein preparation has more than one type of expansin? It is unclear what is intended.

***Claim Rejections - 35 USC § 112***

7. Claims 30-37 are rejected under 35 U.S.C. 112, first paragraph, are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated group 2/3 allergen from grass pollen encoding a polypeptide as defined in SEQ ID NO: 2, does not reasonably provide enablement for any other group 2/3 allergen. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims for the reasons of record stated in Office action mailed on April 4, 2006 as applied to claims 13-21, now cancelled. Applicants traverse the rejection of claims 13-21 in the paper filed on September 5, 2006.

Applicants argue that specification provides enough guidance for one skilled in the art to make and use any group 2/3 pollen allergen. Applicants further argue that the specification provides ample guidance to the skilled artisan seeking to confirm whether a polypeptide is a group 2/3 allergen having  $\beta$ -expansin activity. Applicants further argue that polypeptides suspected of being group 2/3 allergen can be assayed for  $\beta$ -expansin activity using techniques routinely employed by one skilled in the art, including cell wall extension and stress relaxation assays. Applicants further argue that test is not merely quantitative, since a considerable amount of experimentation is possible, and thus instantly claimed invention is enabled for any group 2/3 pollen allergen (response, page 13, lines 15-21; page 14, lines 1-13; page 15, lines 1-11).

Applicant's arguments were fully considered as they apply to new claims 30-37 but were not found persuasive. It is important to note that claim 30 encompasses any group 2/3 pollen allergen from any source and claims 32-33 and 35 further encompass

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any group 2/3 pollen allergen with expansin activity. The claims further encompass that any group 2/3 pollen allergen participates in plant cell wall extension function.

Sampedro et al. teachings clearly indicate existence of group 2/3 pollen allergen lacking expansin activity, implying such group 2/3 pollen allergen would not be expected to participate in cell extension functions as encompassed by the claims. Examiner maintains that in order to elucidate the biological role of a protein such as any group 2/3 pollen allergen, actual experimentation is needed to determine function of said protein under *in vivo* conditions. Furthermore, specification does not provide guidance on conserved functional domains that are shared among group 2/3 pollen allergen from different species so that one skilled in the art can reliably predict their function in plant cell wall extension. Further, in view of high unpredictability of the related art, one skilled in the art would not know how to use any group 2/3 pollen allergen in a method of providing plant cell expansion. Accordingly, Examiner maintains that undue experimentation would have been required by a skilled artisan to determine how to use any group 2/3 pollen allergen in plant cell wall extension.

Accordingly, claims 30-37 are rejected.

8. Claims 30-37 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for the reasons of record stated in Office action mailed April 4, 2006 as applied to claims 13-21, now cancelled. Applicants traverse the rejection of claims 13-21 in the paper filed on September 5, 2006.

Applicants argue that the claims of the present application meet the requirements set forth by written description guidelines. The Applicants further argue that group 2/3 allergen, unlike expansins, lack the structural domain 1, and Applicants describe multiple assays that can be used to determine if a suspected allergen has  $\beta$ -expansin activity so that one skilled in the art would be able to identify a polypeptide as a group 2/3 allergen (response, last paragraph bridging pages 16-17).

Applicant's arguments were fully considered as they apply to claims 30-37 but were not found persuasive. Examiner maintains that the specification does not have adequate written description for a genus of group 2/3 pollen allergen, a genus of 2/3 pollen allergen with  $\beta$ -expansin activity, and one skilled in the art cannot reliably predict the undisclosed structures of Applicant's broadly claimed genus based on the disclosure of SEQ ID NO: 2. Applicants have failed to describe structures of their broadly claimed genus and correlate said structures to the function of plant cell wall expansion. More importantly, Applicants have failed to describe functional conserved domains shared among the undisclosed structures of their broadly claimed genus. Accordingly, there is lack of adequate description to inform a skilled artisan that applicant was in possession of the claimed invention at the time of filing.

Accordingly, claims 30-37 are rejected.

9. Claims 30-37 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 30-37 recite "protein preparation" which introduces **NEW MATTER** into amended claims. The specification does not provide written description support for "protein preparation". This does not comply with written description requirements.

Claims 30 and 37 recite "carrier" which introduces **NEW MATTER** into amended claims. The specification does not provide written description support for "carrier". This does not comply with written description requirements.

Claim 37 recites "buffer" which introduces **NEW MATTER** into amended claim. The specification does not provide written description support for "buffer". This does not comply with written description requirements.

Support for these recitations in the new claims is not found in the original claims or at page 35, lines 24-25 of specification as argued by Applicants (response, page 18, section VII, new claims).

Accordingly, claims 30-37 are rejected.

### ***Claim Rejections - 35 USC § 102***

10. Claims 30-37 are rejected under 35 U.S.C. 102(b) as being anticipated by Ansari et al. (Biochemistry, 28:8665-8670, 1989) and evidenced by Marino et al. (Structure, 7:943-952, August 1999) for the reasons of record stated in the Office action mailed April 4, 2006 as applied to claims 6-7 and 13-21, now cancelled. Applicants traverse the rejection of claims 6-7 and 13-21 in the paper filed on September 5, 2006.

Applicants argue that new claims 30-37 are directed to a protein preparation useful for the expansion of a plant cell wall comprising a group 2/3 pollen allergen having  $\beta$ -expansin activity. Support for these amendments can be found throughout the



specification as filed but particularly in original claims 6-7 and 13-21 and at page 35 lines 24-25. Applicants further argue that nowhere in Ansari or Marino is there a teaching or suggestion that the group 2/3 allergens have  $\beta$ -expansin activity, or that a preparation of the protein (group 2/3 allergen) can be useful in expanding plant's cell wall as now claimed (response, last paragraph of page 17 through the end of second paragraph of page 18)

Applicant's arguments were fully considered as they apply to the new claims but were not found persuasive. Ansari et al. clearly disclose protein preparation comprising a group 2/3 pollen allergen from rye grass. The reference further teaches that the protein preparation comprises a polypeptide having an amino acid sequence which is 100% identical in sequence to instant SEQ ID NO: 2, wherein first 20 amino acids at N-terminal end of said protein comprises a sequence which is 100% identical to SEQ ID NO: 5 (erroneously cited as SEQ ID NO: 15 on page 11, line 10 in the Office action mailed on April 4, 2006). The reference further teaches that protein preparation was made in a medium such as buffer and the protein (2/3 pollen allergen, SEQ ID NO: 2) was purified to homogeneity. See Ansari et al., page 8666, 1<sup>st</sup> paragraph of materials and methods. Office maintains that the property cell expansion due to  $\beta$ -expansin activity is inherent to the amino acid sequence taught in the reference. Furthermore, the property of a group 2/3 allergen encoding a polypeptide that possesses expansin activity which is not affected by DTT is also inherent to the polypeptide taught in the reference as evidenced by the absence of cysteine residues in the amino acid sequence taught in the reference.

Accordingly, claims 30-37 are rejected.

### ***Summary***

11. Claims 30-37 are rejected.

Applicants amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is set to expire within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

### ***Contact Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vinod Kumar whose telephone number is (571) 272-4445. The examiner can normally be reached on 8.30 a.m. to 5.00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for

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published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read 'Ashwin D. Menta', with a stylized, cursive script.

**ASHWIN D. MENTA, PH.D.  
PRIMARY EXAMINER**